

Attachment IX:**Summary of Safety and Effectiveness Information
[510(k) Summary]**

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Synthes Ti Distal Femoral Nail (DFN) is compared to Richard's IMSC Five Nail and Ace's Retrograde Trauma Nail.

The Synthes Ti DFN System is generally intended to stabilize fractures of the distal femur. Specifically, the Ti DFN is intended for supracondylar fractures (including those with intra-articular and/or extra-articular involvement), pathologic fractures, mal-unions, non-unions, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee, fractures distal to a total hip, fractures in the multiply injured patient, fractures in the morbidly obese patient, and fractures in osteoporotic bone. The Ti DFN can be used in either reamed or non-reamed applications.

Richard's IMSC Five Nail is intended to stabilize fractures of the distal femur including supracondylar fractures of the distal femur, including those which extend into the articular surface, pathologic fractures of the distal femur, mal-unions of the distal femur, failed distal femoral osteosynthesis, and distal femur fractures in osteoporotic bone.

Ace's Retrograde Trauma Nail is intended to stabilize fractures of the distal femur including supracondylar fractures of the distal femur, including those with extra-articular comminution and/or intra-articular movement, malunions, non-unions, osteoporosis, osteotomies of the distal femur, failed osteosyntheses of the distal femur, fractures proximal to a total knee, and obese or multiple trauma patients with femoral shaft fractures.

Synthes Ti DFN System is a cannulated and solid locking intramedullary fixation device. The following components make up the DFN system: Transverse Locking Nails, 6.0 mm Ti Locking Screws, 4.9 mm Ti Locking Bolts, and Ti End Caps. Synthes Ti DFN System is manufactured from a titanium alloy.

Synthes Ti DFN has various locking options both proximally and distally. The Ti DFN are available in diameters ranging from 9 mm to 13 mm, and lengths ranging from 160 - 460 mm. The 6.0 mm Ti Locking Screws and 4.9 mm Ti Locking Bolts are used to lock the DFN into place. The Ti End Cap locks the distal 6.0 mm Ti Locking Screw to the Ti DFN.

Based on the information contained in this 510(k), the Ti DFN is at least equivalent to the Richard's IMSC Five Nail and Ace's Retrograde Trauma Nail.